MAR 2 8 2006

VIII. 510(k) Summary

A. Sponsor/Submitter:

Marine Polymer Technologies, Inc.
107 Water Street
Danvers, MA 01923
Phone: 781-270-3200
Fax: 781-270-1133

B. Contact Person

Sergio Finkielsztein
President
Phone: 781-270-3200 x 13

C. Date of Submission:

November 15, 2005

D. Trade (Brand) Name:

Syvekexcel® Vascular Access Hemostasis System

E. Common Name:

Topical Hemostasis Pad/Vascular Clamp

F. Classification Number/ Name:

21 CFR § 870.4450 Vascular Clamp

G. Regulatory Class:

Class II (two)

H. Product Code:

DXC

I. Predicate Devices:

Marine Polymer Technologies, Inc.- SyvekPatch (K984177)
Advanced Vascular Dynamics- CompressAR SuperComfort Disc and Strong Arm SuperComfort System (K040615)
Vascular Solutions, Inc. D-Stat Dry Hemostatic Bandage (K030836)
Vascular Solutions, Inc. D-Stat Clamp Accessory (K050146)
TZ Medical- EZ Hold (K973132)
RADI Medical Systems- Femostop Femoral Compression System (K024107)
RMDS, Inc. Femoral Artery Vascular Pad (K964663)
Abbott Vascular Devices - Chito-Seal™ (K021062)

J. Intended Use:

Syvekexcel® Vascular Access Hemostasis System is intended for use following femoral vascular catheterization procedures to assist in obtaining and maintaining hemostasis.

K. Device Description:

Syvekexcel® Vascular Access Hemostasis System consists of four (4) components in a kit:

1. a Syvekexcel® Patch 3 cm x 4cm lyophilized pad of poly-N-acetylglucosamine with foam backing,
2. a disposable Polypropylene support structure, which snaps on to component 3,
3. a reusable Plexiglas handle, and
4. a Tegaderm® transparent adhesive bandage

Syvekexcel® Vascular Access Hemostasis System is used to apply direct pressure to obtain and maintain hemostasis, in a similar fashion to direct manual pressure on the access site or at a pressure point. After hemostasis has been achieved the Syvekexcel® Patch is covered with the Tegaderm® transparent adhesive bandage.

L. Summary of Substantial Equivalence:

Marine Polymer Technologies has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that Syvekexcel® Vascular Access Hemostasis System is substantially equivalent to currently marketed predicate devices. Syvekexcel® Vascular Access Hemostasis System has essentially the same intended use as the predicate devices. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted. Animal testing was performed to simulate clinical conditions with no adverse effects noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Marine Polymer Technologies, Inc.
c/o Mr. Sergio Finkielsztein
President
107 Water Street
Danvers, MA 01923

Re: K053300
Syvek$_{excel}$® Vascular Access Hemostasis System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: March 3, 2006
Received: March 6, 2006

Dear Mr. Finkielsztein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053300

Indications for Use Statement

510(k) Number K053300

Device Name: Syvek$_{excel}$® Vascular Access Hemostasis System

Indications for use:

Syvek$_{excel}$® Vascular Access Hemostasis System is intended for use following femoral vascular catheterization procedures to assist in obtaining and maintaining hemostasis.

Prescription Use __X__ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053300